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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,184	01/28/2005	John J.R. Mertens	1592 WO/US	8281
7590	03/02/2006		EXAMINER	
Mallinckrodt Inc 675 McDonnell Boulevard PO Box 5840 St Louis, MO 63134			CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/523,184	MERTENS, JOHN J.R.	
	Examiner	Art Unit	
	Yong Chu	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 2/10/2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 2, 4, 7-8, and 12-24 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3, 5-6, and 9-11 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 1/28/2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/4/2005</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claims 4, 7-8, and 12-24 are cancelled by amendment filed on 10 Feb 2006.

Claim 1 is amended by amendment filed on 10 Feb 2006. Therefore, claims 1-3, 5-6, and 9-11 are currently pending in this instant application.

Priority

This application is a 371 of PCT/US03/24436, filed on 01 August 2003.

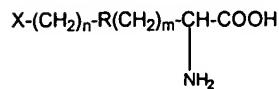
Acknowledgement is made of Applicant's claim for EPO Patent Application 02078228.0 under 35 U.S.C. §119(a-d), filed on 02 August 2002. However, the EPO priority is not granted because the certified EPO Patent Application 02078228.0 is not received by USPTO.

Response to Restriction

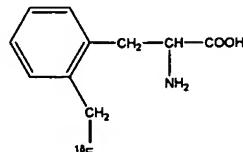
The response to the restriction request *with traverse* by Applicants' representative, Jerad G. Seurer dated on 10 February 2006, has been considered. As a result of two telephone conferences, Examiner has agreed to examine Groups I, II, and III with an appropriate scope as described in the following Status of Scope.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The election of **Group I-III**, directed to products of formula (II),



and the specific compound



, depicted on page 4 of

the Remarks, is acknowledged.

Status of the Claims

Claims 1-3, 5-6, and 9-11 are pending in this application. Claim 2 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and will require separate search considerations under different classification. In the instant case, the withdrawn

claim 2 draws to an analog of formula

$$X-(CH_2)_n-R(CH_2)_m-\overset{NH_2}{\underset{|}{\text{CH}}}-COOH$$

therein R is alkyl group,
which is distinct from aromatic or heteroaromatic ring. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:

Compounds of formula,

$$X-(CH_2)_n-R(CH_2)_m-\overset{NH_2}{\underset{|}{\text{CH}}}-COOH$$

depicted in claim 1, wherein:

X is a radioactive halogen;

m is 0 or 1;

n is 1, 2, 3, 4, 5, or 6; and

R is a substituted aromatic or heteroaromatic ring.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1 (in part, wherein R is (C₁-C₆)alky), 2, 4, 7-8, and 12-24 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. Claims 1, 3, 5-6, and 9-11 are examined.

Specification

Continuing data is not mentioned in the first paragraph of Specification, including PCT§371 and priority data. Correction is required.

The Draw 1 of 2 misses "Fig. 1" and is subject to correction of the informalities. In order to avoid abandonment of this application, correction is required in reply to the Office action by submitting a corrected replacement draw.

The disclosure is objected to because of the following informalities: typo of "80EC", should be 80°C on page 11 and 13; typo "76 M" on line 10 page 14.

Appropriate corrections are required.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 and 3 are rejected under 35 U.S.C. 102 (b) as being anticipated by Wester et al., *The Journal of Nuclear Medicine*, 1999, 40(1), 205-212 (IDS).

Applicants' instant elected invention in claims 1 and 3 teaches a compound of

formula,
$$\begin{array}{c} X-(CH_2)_n-R(CH_2)_m-\underset{NH_2}{\overset{|}{CH}}-COOH \\ | \end{array}$$
, depicted in claim 1, thereof wherein:

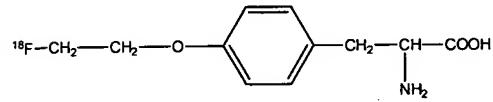
X is a radioactive halogen;

m is 0 or 1;

n is 1, 2, 3, 4, 5, or 6; and

R is a substituted aromatic or heteroaromatic ring.

Wester et al. teach specific compound O-(2-[¹⁸F] fluoroethyl-L-Tyrosine



, *The Journal of Nuclear Medicine*, 1999, 40(1), 205-

212 read on the instant claims 1 wherein:

X is ¹⁸F, a radioactive halogen;

m is 1;

n is 2; and



Therefore, Claims 1 and 3 are rejected under 35 U.S.C. 102 (b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-6, and 9-11, are rejected under 35 U.S.C. 103 (a) as unpatentable over Wester *et al.*, *The Journal of Nuclear Medicine*, 1999, 40(1), 205-212 in view of Sheffer-Dee-Noor *et al.*, *Tetrahedron*, 1994, 50(23), 7009-18.

Applicants instant elected invention in claims 1, 3, 5-6, and 9-11 teach a

compound of formula,
$$\begin{array}{c} X-(\text{CH}_2)_n-\text{R}(\text{CH}_2)_m-\overset{\text{NH}_2}{\underset{|}{\text{CH}}}-\text{COOH} \\ \text{, depicted in claim 1 and a pharmaceutical} \end{array}$$
 composition, thereof wherein:

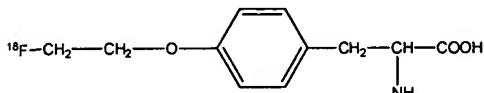
X is a radioactive halogen;

m is 0 or 1;

n is 1, 2, 3, 4, 5, or 6; and

R is a substituted aromatic or heteroaromatic ring.

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Determination of the scope and content of the prior art (MPEP §2141.01)Wester et al. teach a specific compound O-(2-[¹⁸F] fluoroethyl-L-Tyrosine, *The Journal of Nuclear Medicine*, 1999, 40(1),

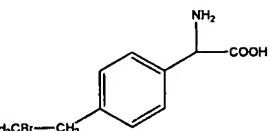
205-212 read on the instant claim 1 wherein:

X is ¹⁸F, a radioactive halogen;

m is 1;

n is 2; and

R is , a substituted aromatic ring.



Sheffer-Dee-Noor et al. teach a specific compound ,

Tetrahedron, 1994, 50(23), 7009-18 read on the instant claim 1 wherein:

X is Br, a halogen;

m is 1;

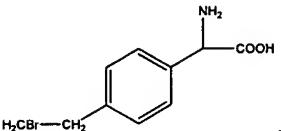
n is 2; and

R is , a substituted aromatic ring.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Wester et al., and the instantly claimed compounds is that Wester et al. does not teach all the ¹⁸F labeled compounds in claims

1, 3, 5-6, and 9-11, but a similar compound. However, Wester et al do teach using the same application for PET diagnosis.

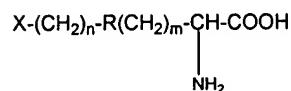


Sheffer-Dee-Noor et al. teach a specific compound $\text{H}_2\text{CBr}-\text{CH}_2-$,

Tetrahedron, 1994, 50(23), 7009-18. Sheffer-Dee-Noor et al. do not teach a compound labeled with [¹⁸F]. However, it is known that Br and F are both halogen.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compounds of Formula



defined in claim 1 with prima facie obvious because it is suggested by combining the two prior arts as described previously. The motivation to make the claimed compounds derives from the expectation that the claimed compounds and compositions are used as tracers in PET as the same way as the compound disclosed as in Wester et al. article.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification discloses a general procedure for synthesis of [¹⁸F]fluorealkyl phenylalanine on page 9-14. However, the specification does not teach how to make other radio labeled compounds, and/or heteroaromatic ring containing compounds, such as pyridine- ring containing compound, as well as other claimed radio-labeled amino acid compounds in such a way as to reasonably convey to one skilled in the relevant art to practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as failing to comply with the written description requirement. The term "substituted" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 5 and 6 are objected because they depend on a cancelled claim 4.

Conclusion

No claims allowed.

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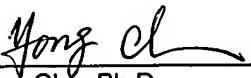
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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